IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	)	Civ. No. 5:13-cv-760

COMPLAINT

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") ("collectively, "Plaintiffs") hereby file this Complaint against Defendant BioDelivery Sciences International, Inc. ("BDSI"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,475,832 ("the '832 patent"), arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202.

2. Pursuant to New Drug Application 22-410, the United States Food and Drug Administration ("FDA") authorized Plaintiffs to market a pharmaceutical drug product used to treat opioid dependence that is sold under the name Suboxone®. Suboxone® is a sublingual, transmucosal film that contains the active ingredients buprenorphine hydrochloride and naloxone

hydrochloride. Plaintiffs have manufactured and continue to manufacture and sell Suboxone® for the U.S. market.

3. BDSI has submitted a New Drug Application under 21 U.S.C. § 355(b)(2) (the "505(b)(2) NDA") to the FDA seeking approval to manufacture and sell a competing pharmaceutical drug product to Suboxone® that contains the same active ingredients and is intended to treat the same medical indications. BDSI intends to market its competing product under the name Bunavail™.

4. BDSI's submission of its application to the FDA constitutes an act of patent infringement under 35 U.S.C. § 271(e). Furthermore, a real and justiciable controversy exists between Plaintiffs and BDSI regarding whether Bunavail™ infringes the '832 patent. Therefore, Plaintiffs also seek a declaration that the sale of BDSI's proposed product will infringe the '832 patent under 35 U.S.C. § 271(a)-(c).

THE PARTIES

5. Plaintiff RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

6. Plaintiff RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

7. Plaintiff MonoSol is a Delaware limited liability company having a principal place of business at 30 Technology Drive, Warren, New Jersey.

8. Defendant BDSI is a Delaware corporation having a principal place of business at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271.

10. This Court has personal jurisdiction over BDSI because BDSI resides in this judicial district.

11. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

12. Plaintiff RBP UK is the lawful owner of the ’832 patent. The ’832 patent, entitled “Sublingual and Buccal Film Compositions,” was duly and legally issued on July 2, 2013, to Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. The named inventors assigned their rights to MonoSol, who subsequently assigned its rights in the ‘832 patent to Reckitt Benckiser Healthcare (UK) Limited, which then assigned its rights to RBP UK. MonoSol manufactures Suboxone® for the US market. A true copy of the ’832 patent is attached hereto as Exhibit A.

PLAINTIFFS’ SUBOXONE® PRODUCTS

13. Plaintiff RBP is the owner of New Drug Application (“NDA”) No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

14. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. Plaintiff RBP has sold Suboxone® sublingual film since its approval.

15. RBP also owns NDA No. 20-733 for Suboxone® sublingual tablet. Suboxone® sublingual tablet contains the same active ingredients as Suboxone® sublingual film (buprenorphine hydrochloride and naloxone hydrochloride).

BDSI's ATTEMPT TO CIRCUMVENT THE HATCH-WAXMAN ACT

16. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

17. Under 21 U.S.C. § 355(b)(1), the NDA applicant is required to submit extensive testing and safety information concerning the drug ("505(b)(1) applications"). In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

18. Both the NDA for the Suboxone® sublingual film and the NDA for the Suboxone® sublingual tablet are 505(b)(1) applications. The '832 patent is listed in the FDA's Orange Book as covering Suboxone® sublingual film. There are no unexpired patents listed on the Orange Book for Suboxone® sublingual tablet.

19. The Hatch-Waxman Act amended the FD&C Act to provide for applications filed under 21 U.S.C. § 355(b)(2) ("505(b)(2) applications"), which allow applicants to obtain FDA approval for other versions of previously-approved drugs without having to repeat the extensive

testing required for a new drug application. Section 505(b)(2) applications can rely, in part, on FDA's previous findings of safety and efficacy for an approved drug product.

20. If a 505(b)(2) applicant relies on previous FDA findings of safety and efficacy for a previously-approved drug product, the 505(b)(2) applicant must identify the drug application which formed the basis for FDA approval ("Reference Listed Drug" or "RLD").

21. Under 21 U.S.C. § 355(b)(2)(A), the 505(b)(2) applicant must make one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV" certifications).

22. If a 505(b)(2) applicant makes a Paragraph IV certification, the Hatch-Waxman Act, 21 U.S.C. § 355(b)(3), requires the 505(b)(2) applicant to give notice to the patent owner of the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed.

23. If the 505(b)(2) application includes a Paragraph IV certification, the patent owner can file an infringement action within 45 days of receiving the notice of Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(c)(3)(C). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

24. On July 31, 2013, Defendant BDSI submitted a 505(b)(2) NDA to the FDA, seeking approval to engage in the commercial manufacture and/or sale of Bunavail™. See BDSI's August 1, 2013 press release, attached as Exhibit B. BDSI has not made a certification under 21 U.S.C. § 355(b)(2)(A)(iv) as to the '832 patent or any other patent.

25. Although the most similar alternative to Defendant BDSI's Bunavail™ film product is Suboxone® sublingual film (NDA No. 22-410), BDSI's 505(b)(2) application uses Suboxone® sublingual tablet (NDA No. 20-733) as the reference drug.

26. On information and belief, BDSI's Bunavail™ product, like Suboxone® film and unlike Suboxone® tablet, is a mucoadhesive, erodible, high surface area to weight ratio polymeric dosage form, that is orally delivered and applied to a mucosal surface. Additionally, the excipient profile and associated functionality are distinct from those of the Suboxone® tablet. *See* MonoSol's FDA Citizen Petition dated August 12, 2013, attached as Exhibit C. According to BDSI, Bunavail™ uses BDSI's BioErodible MucoAdhesive ("BEMA") drug delivery technology.

27. Further, while BDSI has not yet announced the strength of the Bunavail™ product, BDSI has enrolled patients into a clinical trial with the following strengths: 3.5/0.6 mg and 5.25/0.9 mg (buprenorphine/naloxone). The strengths of BDSI's buprenorphine/naloxone product in the clinical trial are "most similar" to the 4 mg/1 mg (buprenorphine/naloxone) strength of the Suboxone® film product. *See* BDSI, Clinical Trial, An Open Label Study to Assess the Safety and Tolerability of BEMA® Buprenorphine NX In Opioid Dependent Subjects, attached as Exhibit D.

28. BDSI's decision to use Suboxone® tablet as the reference drug instead of Suboxone® film was a blatant attempt to avoid providing RBP with a notice of Paragraph IV

certification to the ’832 patent, thereby preventing RBP from filing an infringement action within 45 days of receiving the notice of Paragraph IV certification and obtaining a 30-month injunction against BDSI, as permitted under 21 U.S.C. § 355(c)(3)(C).

29. In a Citizen’s Petition dated December 2, 2011, Docket No. FDA-2011-P-0869, Plaintiffs requested that the FDA “[r]efuse the submission of any 505(b)(2) NDA for a buprenorphine/naloxone drug product consisting of a polymer film for application to the oral mucosal membranes unless such 505(b)(2) NDA references NDA No. # 22-410 (Suboxone®), which is the NDA for the sublingual film formulation of this product, and makes the appropriate certifications with respect to all patents listed for NDA #22-410.”

30. After BDSI submitted its 505(b)(2) application, a different FDA regulation applied; and on August 12, 2013, the Plaintiffs re-filed the Citizen’s Petition which was assigned docket number FDA-2013-P-0995.

31. On September 18, 2013, the FDA responded to both Citizen’s Petitions, granting them in part and denying them in part (attached as Exhibit E). Importantly, the FDA did not reject BDSI’s 505(b)(2) application and found that “[i]n the absence of a pharmaceutically equivalent product, a 505(b)(2) applicant is not required to select a listed drug that is the ‘most similar’ (in [petitioner’s] view) to the proposed product as long as reliance on the listed drug is scientifically justified.”

32. Bunavail™ will compete directly with Suboxone® sublingual film. In its 2012 annual report, attached as Exhibit F, BDSI stated that:

> Currently, we remain on track to file the NDA for BUNAVAIL™ with the U.S. Food and Drug Administration (FDA) in mid-summer 2013, putting BDSI in the position to introduce the next branded transmucosal buprenorphine/naloxone film into the marketplace for opioid dependence. This filing will include data from our positive pivotal bioequivalence study completed in the second half of 2012, as well as data from the

> "Suboxone conversion" safety study which completed in early 2013. In the latter, we were able to demonstrate favorable tolerability of BUNAVAIL™ in opioid dependent subjects when switched from Suboxone. We believe that BUNAVAIL™ will offer an alternative treatment option with advantages over Suboxone, a product that generated sales in excess of $1.5 billion in 2012, according to Wolters Kluwer. As we stated earlier this year, we are evaluating strategic options for the commercialization of BUNAVAIL™, including partnerships as well as leading the commercialization on our own. We plan to finalize this strategy and decision in the second half of 2013.

33. In a press release dated August 9, 2013, attached as Exhibit G, BDSI stated that "[i]f approved, BUNAVAIL will be the first buccal film dosage form containing buprenorphine for the treatment of opioid dependence that will compete with the market leader Suboxone . . . ."

34. On October 9, 2013, BDSI issued another press release, attached as Exhibit H, announcing that its NDA for Bunavail™ "has been accepted for filing by the [FDA]" and that "the review of the BUNAVAIL NDA is expected to be completed by early June 2014."

35. Plaintiffs have been deprived of relief available under the Hatch-Waxman Act, including a stay by the FDA of any approval of BDSI's 505(b)(2) NDA until "the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) of this section or such shorter or longer period as the court may order." 21 U.S.C. § 355(c)(3)(C).

BDSI's REPEATED PATTERN OF INFRINGEMENT, FILING ADVERSARY PROCEEDINGS AGAINST MONOSOL'S PATENTS, AND DELAY

36. In an action pending in the United States District Court for the District of New Jersey, Docket No. 3:10-cv-05695-FLW-DEA ("the New Jersey Action"), Plaintiff MonoSol asserted patent infringement claims against BDSI in connection with the Onsolis™ film product. Plaintiff MonoSol asserted infringement of U.S. Patent No. 7,425,292 ("the '292 patent") as well as U.S. Patents Nos. 7,357,891 ("the '891 patent") and 7,824,588 ("the '588 patent").

37. The Onsolis™ film product, like Bunavail™ also, according to BDSI, uses BDSI's BEMA film technology.

38. The '292 and '891 patents were subject to *ex parte* reexamination proceedings before the United States Patent and Trademark Office ("USPTO"), initiated by BDSI in Application Serial No. 90/012,097 and Application Serial No. 90/012,098, respectively. The '588 patent is also subject to an *inter partes* reexamination proceeding before the USPTO, Application Serial No. 95/001,753, requested by BDSI.

39. BDSI moved to stay the proceedings in the New Jersey Action pending resolution by the USPTO of the *inter partes* reexamination of the '588 patent and the *ex parte* reexaminations of the '292 and '891 patents. The motion to stay was granted on March 7, 2012.

40. The *inter partes* reexamination of the '588 patent is still pending before the USPTO, but the *ex parte* reexaminations of the '292 and '891 patents have been resolved. The USPTO issued reexamination certificates for both the '292 and '891 patents on July 3, 2012 and August 21, 2012, respectively. Having failed to invalidate the '292 and '891 patents through the *ex parte* reexaminations, on June 12, 2013, BDSI filed petitions to institute *inter partes* review of the '292 and '891 patents with the USPTO, Case No. IPR2013-00315 and Case No. IPR2013-00316, respectively. The petitions are still pending before the USPTO.

41. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and Defendant BDSI regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Bunavail™ according to BDSI's 505(b)(2) NDA, will infringe one or more claims of the patent-in-suit. Plaintiffs are entitled to a declaration that the making, using, sale, offer for sale, and importation

into the United States of Bunavail™ according to BDSI's 505(b)(2) NDA would infringe one or more claims of the patent-in-suit.

COUNT I
(Declaratory Judgment as to U.S. Patent No. 8,475,832)

42. Plaintiffs reallege paragraphs 1-41 above as if fully set forth herein.

43. On information and belief, BDSI's Bunavail™ product is covered by one or more claims of the '832 patent.

44. On information and belief, unless enjoined by this Court, BDSI intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Bunavail™, upon approval of its pending 505(b)(2) application.

45. Pursuant to 35 U.S.C. § 271(a)-(c), Defendant BDSI's commercial manufacture, use, sale, offer for sale, or importation into the United States, of Bunavail™ will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '832 patent.

46. On information and belief, by seeking approval to distribute BDSI's Bunavail™, BDSI intends to cause others -- specifically, for example, medical professionals and patients -- to perform acts that BDSI knows will infringe one or more claims of the '832 patent.

47. On information and belief, BDSI knows (a) that its Bunavail™ product is especially made or adapted for use in infringing one or more claims of the '832 patent and (b) that the Bunavail™ product is not suitable for any substantial noninfringing use.

48. The acts of infringement by BDSI set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

49. There is a real, substantial, and continuing justiciable case and controversy between Plaintiffs and Defendant BDSI regarding whether Defendant BDSI's commercial manufacture and/or sale of Bunavail™ will infringe one or more claims of the '832 patent. Plaintiffs are entitled to a declaration that such activities would infringe one or more claims of the '832 patent.

COUNT II
(Infringement of U.S. Patent No. 8,475,832)

50. Plaintiffs reallege paragraphs 1-49 above as if fully set forth herein.

51. The submission of BDSI's 505(b)(2) NDA is an act of infringement by BDSI of one or more claims of the '832 patent under 35 U.S.C. § 271(e)(2)(A), which provides that:

> It shall be an act of infringement to submit—
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,
>
> . . .
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

52. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the FDA set the effective date of approval for BDSI's 505(b)(2) NDA to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of BDSI's Bunavail™ would infringe the '832 patent under 35 U.S.C. § 271(a)-(c);

B. A judgment that BDSI has infringed the '832 patent by submitting BDSI's 505(b)(2) NDA under 35 U.S.C. § 271(e)(2);

C. Preliminary and permanent injunctions, restraining and enjoining BDSI, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from contributing to and/or inducing the use of methods, claimed in the '832 patent;

D. An Order that the effective date of any approval of BDSI's 505(b)(2) NDA be a date that is not earlier than the expiration of the '832 patent, including any extensions thereof and any later expiration of exclusivity associated with the patent;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest, if Defendant BDSI commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States BDSI's Bunavail™ before the expiration of the '832 patent, including any extensions; and

G. Any and all other relief as the Court deems just and proper.

Dated: October 29, 2013

Respectfully submitted,

/s/ Michael E. Ray

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